

UNITED STATES OF AMERICA
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,

Plaintiff,

v.

SARDINHA SAUSAGE, INC.,

and

EDWARD SARDINHA,

Defendants.

04 11797 GAO

CIVIL ACTION
NO.

DECLARATION OF WILLIAM J. SMITH

DECLARATION OF WILLIAM J. SMITH

I, WILLIAM C. SMITH, make the following declaration in connection with a complaint by the government seeking to enforce and restrain and prevent violations of the Federal Meat Inspection Act and the Poultry Products Inspection Act. I am aware that this declaration will be filed with the United States District Court for the District of Massachusetts, and that it is the legal equivalent of a statement under oath. This declaration is based upon my personal knowledge, the files and records of the USDA, and upon facts made known to me in my capacity as an official of the USDA.

1. I am the Assistant Administrator of the Office of Field Operations for the Food Safety and Inspection Service (FSIS), an agency of the United States Department of Agriculture (USDA). I have been employed by the USDA-FSIS for over twenty-six (26) years and have held my current position of Assistant Administrator since May 2002. I have previously served as Assistant Deputy Administrator for District Inspection Operations; Executive Director; Acting Regional Director and Deputy Regional Director for the Northeast Region; Director of the Processed Products Inspection Division; Processing Staff Officer; Regional Quality Control Specialist; and food inspector. I played a key role in development and implementation of the Pathogen Reduction and Hazard Analysis and Critical Control Point (HACCP) rule in federally and state inspected establishments and continue to play in critical role in the development and implementation of various inspectional and policy matters to protect and ensure the public health, including requirements to reduce and prevent contamination from pathogens such as *Listeria monocytogenes*. I hold a Bachelor of Science degree in Biological Life Sciences from Kansas State University, Manhattan, Kansas.

2. As Assistant Administrator, Office of Field Operations, FSIS, USDA, I have responsibility for administration, management and oversight of program activities for providing inspection services, under the Federal Meat Inspection Act (21 USC 601 *et seq.*)(FMIA) and Poultry Products Inspection Act (21 USC 451 *et seq.*)(PPIA) to about 6500 meat and poultry slaughter and processing establishments throughout the United States. In this role, I administer, verify compliance with, and enforce, *inter alia*, the FMIA, PPIA and the regulations promulgated thereunder in order to ensure that meat and poultry food products produced and distributed to consumers from federally inspected establishments are safe, wholesome, not adulterated, and properly marked, labeled and packaged. See 21 U.S.C. 451, 602. I am responsible for regulatory activities carried out by a network of 15 district offices and more than 8,000 Federal inspectors, veterinarians and enforcement investigation and analysis officers in domestic meat and poultry plants and for conducting compliance and enforcement activities to address situations where unsafe, unwholesome and inaccurately labeled products have been produced or marketed.

3. Under the FMIA and PPIA, the FSIS inspects all meat and poultry and meat and poultry food products sold in interstate and foreign commerce to determine that such products are produced under sanitary conditions, are not adulterated, and are from animals that are not diseased. See generally 21 U.S.C. 454-465, 603-619. At the center of the USDA public health strategy are the Sanitation Performance Standards (SPS)(9 C.F.R. 416.1 – 416.6), the Sanitation Standard Operating Procedures (SSOP)(9 C.F.R. 416.11 – 416.17), and the Hazard Analysis and Critical Control Point (HACCP) systems (9 C.F.R. 417.1 – 417.8) regulations, which require, generally, that all federally inspected slaughter and processing establishments develop and implement effective sanitation and process control systems to address food safety hazards that are reasonably likely to occur in their operations and ensure that products are produced in a

sanitary environment, free from filth, pathogens, and other contaminants that could render the products adulterated or otherwise unsafe for consumers.

4. As part of its public health strategy to protect consumers, FSIS has instituted a number of policies and regulatory requirements to prevent, control, eliminate and safeguard consumer food channels from meat and poultry products adulterated or contaminated by pathogens. Raw meat products are known to contain pathogenic microorganisms, such as *Salmonella*, *Campylobacter*, *Escherichia coli* O157:H7, and *Listeria monocytogenes* (Lm.), that can cause foodborne illness (from gastroenteritis, fever, headache, flu-like symptoms, body ache, and loss of balance to convulsions, miscarriage, and death) if they are not destroyed by an adequate lethality process. Ready-to-eat (RTE) products, which are increasing in consumer use because the consumer does not have to apply a lethality step (cooking) prior to consuming product also present particular concerns regarding pathogenic contamination, with Lm. being of particular risk.

5. Based on public health data and the results of a risk assessment, FSIS established new regulatory requirements, through rulemaking, for federally inspected plants regarding the "Control of *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products." See 68 Fed. Reg. 34207 (June 6, 2003). The regulation requires plants that produce certain ready-to-eat (RTE) product prevent product adulteration by the pathogenic environmental contaminant *Listeria monocytogenes*. In particular, plants that product RTE product exposed to the environment after lethality treatments and that support the growth of Lm. are required to address appropriate controls to prevent adulteration by Lm. in the plant's HACCP or SSOP systems or through a prerequisite program.

6. The FSIS role under this public health regulatory framework is to verify that a plant is controlling sanitation and its processing operations and consistently producing meat and poultry food products that comply with the food safety requirements of the FMIA and PPIA. In this regard, FSIS inspectors are required, under the FMIA and PPIA, to adjudge the sanitary conditions of each establishment and are not to pass meat products unless the inspectors can find that the products have not been prepared, packed, or held under insanitary conditions whereby the products may have become contaminated with filth or may be otherwise rendered injurious to health. See 21 U.S.C. 453(g), 456, 601(m), 608. Generally, before FSIS inspectors can mark a product as "inspected and passed," the FMIA and PPIA require that the inspectors make the affirmative determination that the meat product is not adulterated. See 21 U.S.C. 456, 608. FSIS inspectors cannot determine that a product is not adulterated when a plant's sanitation and food safety control system are not properly controlled, not properly monitored, not implemented or are inadequate, or where establishments are not recording and maintaining records relative to the implementation of their sanitation and food safety systems.

7. The effective oversight, verification and enforcement of the SPS, SSOP, HACCP, Lm., and other regulations is crucial to ensuring that plants produce safe meat and poultry and meat and poultry food products. When plants fail to comply with these critical food safety and sanitation requirements, FSIS applies its inspection and enforcement authorities to carry out its public health mission. These authorities include issuance of Noncompliance Reports (NRs), which provide notice to the plant when requirements of the regulations are not being met, and the more formal enforcement actions including controlling potentially unsafe product or formal administrative action to withdraw a plant's grant of federal inspection service.

8. Sardinha's Sausage, Inc., is in the business of preparing, freezing, packaging, labeling, selling and offering for sale and transportation meat, poultry and meat and poultry food products, including raw and ready-to-eat products, specifically including marinated pork, raw marinated poultry, fully cooked pork chourico, fully cooked chicken chourico, fully cooked pork linguica, fully cooked turkey linguica, and fully cooked franks. This kind of business is required by the FMIA and PPIA to operate under Federal inspection. Sardinha's has operated under a grant of inspection from USDA, as establishment 17995/P-17995, under the authority of the FMIA and PPIA, and, when in operation, is subject to daily USDA inspection. Sardinha's first received a grant of inspection from USDA in March of 1991. Sardinha's offices and operations are located at 206 Brownell Street, Fall River, Massachusetts 02720.

9. When Sardinha applied for and received federal inspection service it agreed and certified that it would conform strictly to applicable Federal law and regulations pertaining to meat and poultry inspection and operations under the FMIA and PPIA. See Attachment 1.

10. The agency regulations require establishments, such as Sardinha's Sausage, to develop, implement, and effectively maintain, under HACCP, critical control points (CCPs) in the production process to control identified hazards. An adequate lethality step(s) is one of the CCPs in an establishments' HACCP plan for RTE products, such as those produced by Sardinha's. If such CCPs for RTE products are not properly implemented and monitored, or appropriate corrective actions taken in response to a process deviation, the potential risk for foodborne illness is significant. Additionally, if the establishment does not have an adequate sanitation program in place, this too can have a significant impact on the food safety characteristics of an RTE product.

11. Sardinha's Sausage and other federally inspected plants also must properly develop, implement and effectively maintain a sanitation program (SPS and SSOP) to prevent direct product contamination or adulteration in the production process. This is especially critical with respect to RTE products, which present a risk of contamination from *Listeria monocytogenes*.

12. *Listeria monocytogenes* (Lm.) is a bacterium that is ubiquitous in nature. As such, it can establish niches in various locations in an establishment, such as on process equipment and on food contact surfaces, if proper sanitation practices are not conducted. Therefore, if not controlled, Lm. can contaminate a fully cooked product after the cooking (lethality) step is completed. Because Lm. can grow in food products held under refrigerated conditions, contamination of RTE product post-lethality can pose a significant health threat to consumers. If an inadequate sanitation program exists in the establishment, RTE product would not only be subjected to the possibility of Lm. contamination, the product could also be re-contaminated with other pathogens that are present in or on the raw product ingredients. Such contamination would increase the significance of the food safety risk of the RTE product.

13. I am aware of a significant history of noncompliance and food safety concerns at Sardinha's Sausage. A review of the verification and compliance information documented by FSIS personnel at Sardinha's from February 2000 to April 2004 shows repeated instances of insanitary conditions, direct product contamination, non-compliance with the Lm. regulations, and HACCP regulatory non-compliance, including lack of documentation to support adequate lethality. This information indicates that this establishment has not taken effective corrective and/or preventive measures to ensure product safety.

14. Specifically, Noncompliance Records (NR's) issued by FSIS inspectors to Sardinha's between December 2003 and April 2004 document extensive violations of the food safety and sanitation regulations. These violations included the failure of the plant to properly conduct pre-operational sanitation procedures; direct contamination of RTE sausage by dripping condensation from unsanitary overhead refrigeration units; packing of RTE sausage in the raw product area; and, inadequate recordkeeping and improper testing, sampling and collection methods for Lm.

15. The RTE sausage products produced at Sardinha's, such as "Linguica," which is a seasoned and spiced Portuguese sausage that is generally slow smoked and cooked in a smokehouse, would represent a significant health risk when the product does not receive adequate lethality or is processed under insanitary conditions that can cause product contamination or adulteration.

16. Based on these documented food safety and sanitation issues, which included repetitive noncompliance with the agency's SSOP, SPS, HACCP and Lm. requirements, on April 15, 2004, FSIS instated the suspension of the assignment of inspectors at Sardinha's, suspending the plant from producing product for the mark of federal inspection service or from otherwise conducting any operations required to be conducted under federal inspection.

17. Previously, on October 10, 2003, FSIS notified Sardinha's in writing that the plant had failed to develop and implement effective measures to control and test for *Listeria monocytogenes* (Lm.), as required by the agency regulations. The written notice provided Sardinha's with the opportunity to make corrections before the agency imposed enforcement action, such as suspending inspected operations.

18. On December 18, 2003, FSIS withheld the marks of USDA inspection for certain RTE products produced by Sardinha's and suspended inspected operations when the plant did not appropriately address the noncompliance with the Lm. regulations identified to the plant in October 2003.

19. FSIS had previously initiated enforcement action at Sardinha's in February 2000, including temporarily suspending inspection service to the plant, because of serious, persistent and recurring insanitary conditions and food safety systems inadequacies.

20. Mr. Sardinha, the firm's operator, received written notice of each of these actions and was aware that the plant was precluded from producing and selling products requiring federal inspection during the period of the suspension at the plant.

21. I am aware that FSIS investigators documented information alleging that Sardinha's produced and shipped non-federally inspected product after FSIS suspended inspection service to Sardinha's on April 15, 2004 because of the food safety concerns documented at the establishment.

22. Because of the agency's public health concerns, in a letter dated May 18, 2004, Mr. Scott Safian, Director of the FSIS Evaluation and Enforcement Division, advised Mr. Sardinha of the agency's intent to file a complaint to withdraw the firm's grant of Federal inspection service. See Attachment 2.


23. On May 28, 2004, FSIS filed a formal administrative complaint to withdraw the grant of federal inspection service from Sardinha's Sausage. See Attachment 3. The complaint alleged numerous and repetitive violations of FSIS sanitation and food safety requirements and that Sardinha's had produced, sold, distributed and marked meat produces in commerce without Federal inspection in violation of the FMIA.

24. Based on this information, my knowledge of the current and previous noncompliance and food safety issues at Sardinha's Sausage, and my extensive knowledge of food safety and public health principles, including concerns regarding the presence and spread of Lm. in ready-to-eat products, such as pork chourico, chicken chourico, pork linguica, turkey linguica and franks, I am greatly concerned, from a regulatory and public health perspective, that Sardinha's was found to have, and allegedly continues to, produced and shipped product to consumers that had not been subject to FSIS verification and inspection oversight, as required by the FMIA and PPIA, to protect the health, welfare and safety of the consuming public.

25. FSIS views the type of violations by Sardinha's as serious in nature, particularly given the failure to voluntarily comply after receiving written notice of warning. Sardinha's has demonstrated a lack of regard for the health and welfare of the consuming public, the agency's inspectional authorities and requirements and that it has no intention to comply with the Acts.

26. Based on the extensive and repeated history of noncompliance and the potential harm to the public, FSIS believes that, absent an injunction, Sardinha's will continue to violate the FMIA and the PPIA, and the public interest will be in jeopardy.

I declare, under pain and penalty of perjury, that the foregoing is true and correct to the best of my knowledge, on this 30 day of July 2004.



WILLIAM C. SMITH
ASSISTANT ADMINISTRATOR
OFFICE OF FIELD OPERATIONS
FOOD SAFETY AND INSPECTION SERVICE